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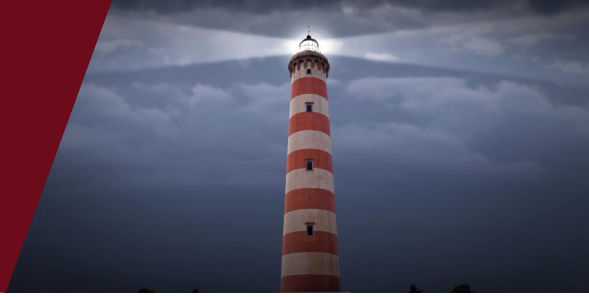

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Biosimilar Product Approval and the Implications of Sandoz v Amgen

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The U.S. Supreme Court's much-awaited decision in *Sandoz Inc. v. Amgen Inc.*, 2017 BL 198127, U.S., No. 15-1039, 6/12/17 is favorable to biosimilar applicants on two key sections of biosimilars law but many questions remain that will need to be addressed through litigation or regulation under this complex new regulatory regime.

On June 12, 2017, in a unanimous decision authored by Justice Clarence Thomas, the Court addressed two critical questions in the biosimilar approval mechanisms adopted in the Biologics Price Competition and Innovation Act of 2009 (''BPCIA'' or ''Biosimilars Act''). Specifically, the Court considered: (1) whether a federal injunction is available to enforce the BPCIA provision that a biosimilar applicant (''applicant,'' *i.e.*, a company seeking approval to market a biosimilar) engage in the ''patent dance'' by providing the reference product sponsor (''sponsor,'' *i.e.*, the company that markets the original biologic drug) a copy of its biologics license application and certain related manufacturing information, and (2) whether the BPCIA's 180 days' premarketing notice provision must be satisfied after the U.S. Food & Drug Administration (''FDA'') has approved the applicant's biosimilar application. The short answer to both is no. However, other BPCIA-related questions and new questions raised by this decision still need to be resolved. Some strategic implications arising from this decision are considered below.

Question #1: The Availability of Injunctive Relief to Enforce the Provision That the Applicant Provide a Copy of the Biosimilar Application

The BPCIA provides an abbreviated pathway for an applicant to obtain FDA approval of a biologic drug that is biosimilar or interchangeable to an already licensed biological drug (*i.e.*, reference product). 42 U.S.C. § 262(k). The BPCIA also provides procedures for resolving patent disputes between the applicant and the sponsor. 42 U.S.C. § 262(l). Under the BPCIA, within 20 days after the FDA accepts an applicant's biosimilar application for review, the applicant ''shall provide'' the sponsor with a copy of the application and information about how the biosimilar is manufactured. 42 U.S.C. § 262(l)(2)(A).

On the first question, *i.e.*, whether a federal injunction is available to enforce the provision that an applicant provide the sponsor a copy of the applicant's biologics

license application and certain related manufacturing information, the U.S. Court of Appeals for the Federal Circuit had relied on 35 U.S.C. § 271(e)(4), which provides remedies for an act of artificial infringement, to determine that no federal injunctive relief was available. The Supreme Court affirmed the result but noted that the Federal Circuit's reasoning was incorrect. Specifically, the Supreme Court held that the act of filing the biosimilar application is the artificial act of infringement, not the applicant's failure to disclose its application and manufacturing information, and, thus, no remedy for failure to comply exists under 35 U.S.C. §271(e)(4). Rather, the Court held that 42 U.S.C. § 262(l)(9)(C) provided the remedy for an applicant's failure to disclose its application and manufacturing information. The Court reasoned that 42 U.S.C. § 262(l)(9)(C), by authorizing the sponsor but not the applicant to bring an immediate declaratory-judgment action for artificial infringement as defined in 42 U.S.C. § 271(e)(2)(C)(ii), ''vests in the sponsor the control that the applicant would otherwise have exercised over the scope and timing of the patent litigation [and] deprives the applicant of the certainty that it could have obtained by bringing a declaratory-judgment action prior to marketing its product.'' Slip op. at 12. The Court held that ''[t]he remedy provided by § 262(l)(9)(C) excludes all other federal remedies, including injunctive relief.'' *Id.*

Although holding that a federal injunction is not available to enforce the provisions of 42 U.S.C. § 262(l)(2)(A) that an applicant ''shall provide'' the sponsor with a copy of the biosimilar application and manufacturing information, the Court did not expressly decide if this provision was a ''mandatory'' requirement (as advocated by Amgen) or a ''condition precedent'' to participation in the patent dance (as advocated by Sandoz). Slip op. at 13-15. Whether the provision is mandatory is relevant in considering whether Amgen could be entitled to injunctive relief under California's unfair competition law, as pled by Amgen, because California's unfair competition law requires there be ''unlawful'' conduct for there to be a remedy. If providing the application and information is mandatory, then Sandoz's failure to provide it could be ''unlawful'' conduct entitling Amgen to state-law injunctive relief. If providing the application and information is optional, Amgen would likely not be entitled to state-law injunctive relief.

The Court did not address the issue of whether California's unfair competition law provided for injunctive relief because that issue did not present a question of federal law. Slip op. at 14. Rather, the Court remanded this issue to the Federal Circuit for reconsideration because its earlier ruling, holding that California's unfair competition law did not provide a remedy, was decided on an incorrect interpretation of the available remedies for failing to comply with provisions of the BPCIA. Thus, the availability of injunctive relief for Amgen under California's unfair competition law will need to be reconsidered by the Federal Circuit. Amgen, however, will not be entitled to injunctive relief under California's unfair competition law if the Federal Circuit holds, as it did in its earlier ruling, that California's unfair competition law only provides a state-law remedy when the underlying statute does not specify an ''expressly exclusive'' remedy and holds further that the BPCIA provides the only remedy for an applicant failing to disclose its biosimilar application and manufacturing information. Of course, the availability of state-law injunctive relief, under any state law, will be moot if the Federal Circuit holds on remand that the BPCIA preempts any state-law remedy.

A holding by the Federal Circuit that the provisions of 42 U.S.C. § 262(l)(2)(A) are mandatory could have other implications. For example, in its rule-making capacity, the FDA could require that applicants submit a statement with a biosimilar application confirming that they have met the provisions of 42 U.S.C. § 262(l)(2)(A) before the FDA will consider (or make a final decision on) the biosimilar application. Such a rule, mandating that an applicant provide the sponsor with a copy of the bio-similar application and manufacturing information to have the application considered (or approved) by the FDA, could effectively render irrelevant the Supreme Court's holding that the BPCIA does not provide a mechanism for a sponsor to force an applicant to disclose its application and manufacturing information under 42 U.S.C. § 262(l)(2)(A). Indeed, Justice Stephen Breyer's concurrence asserted that deference should be given to the FDA's interpretation of the BPCIA. Concurrence at 1.

Additionally, the Supreme Court suggested in a footnote that an applicant's failure to provide the sponsor with a copy of the biosimilar application

and manufacturing information could be a factor considered by a district court in deciding whether to grant a preliminary injunction against marketing a biosimilar in view of a sponsor's patent rights. Slip op. at footnote 2 (stating ''we express no view on whether a district court could take into account an applicant's violation of § 262(l)(2)(A) (or any other BPCIA procedural requirement) in deciding whether to grant a preliminary injunction under 35 U. S. C. § 271(e)(4)(B) or § 283 against marketing the biosimilar'').

Thus, although the Court held that federal injunctive relief is unavailable to sponsors as a mechanism to force an applicant to provide the sponsor with a copy of the biosimilar application and manufacturing information, several issues remain that will need to be ad- dressed on remand to the Federal Circuit or in future litigation—or that may be affected by future FDA rule-making relating to the biosimilar approval process under the BPCIA.

Question #2: Timing of the Notice of Commercial Marketing

Following an applicant's disclosure of its application and manufacturing information, the BPCIA provides that the parties exchange information in the so-called patent dance to identify relevant patents and legal arguments that might be raised in future litigation. 42 U.S.C. § 262(l)(3). Following this exchange, the BPCIA channels the parties into two phases of patent litigation. In the first phase, the parties identify patents that they would like to litigate immediately. The second phase involves patents on the parties' § 262(l)(3) lists that were not litigated in the first phase, and is triggered when the applicant gives the sponsor notice, pursuant to 42 U.S.C. § 262(l)(8)(A), at least 180 days prior to commercially marketing the biosimilar.

Concerning the second question, *i.e.*, whether the applicant may provide its 180-day pre-marketing notice *before* the applicant has obtained FDA approval, the Supreme Court held that the applicant can provide notice *before or after* receiving FDA approval. The Court held that this construction is consistent with the plain language of 42 U.S.C. § 262(l)(8)(A) and the statutory context. In particular, the Court noted that if Congress had intended to impose *two* timing requirements on providing notice, *i.e.*, providing notice after FDA approval *and* at least 180 days before the marketing of the biosimilar, it would have used different language, such as was used in another section of the statute where a dual-timing requirement is specified. Slip op. at 16, citing 42 U.S.C. § 262(l)(8)(B).

In coming to this holding, the Court rejected Amgen's textual arguments for requiring FDA approval before effective notice. Slip op. at 17. According to the Court, Congress' use of the phrase ''biological product licensed under subsection (k)'' in the notice provision did not distinguish from its use of the phrase ''the biological product that is the subject of'' the application elsewhere in the BPCIA. The Court also dismissed Amgen's policy arguments, suggesting that policy issues should be addressed by Congress. The Court found the plain language of the statute clear and, therefore, did not see a need to address any policy considerations. Slip op. at 18. The Court thus held that an applicant need not wait for the FDA to approve its application before providing its commercial marketing notice. *Id.*

Applicants can now take comfort knowing that a notice of commercial marketing is effective whenever it is given at least 180 days before launch, regardless of whether the biosimilar application has been approved. The Court's decision on this issue is helpful to applicants not only for providing a measure of certainty but also for allowing biosimilar drugs to potentially be sold 12 years after the reference product was approved. By contrast, the Federal Circuit's interpretation of the notice provision had effectively given the reference product an additional 180 days of market exclusivity beyond the 12 years of protection during which the FDA could not approve a biosimilar application.

The Federal Circuit ruled that the applicant must provide notice of commercial marketing. *Amgen Inc. v. Apotex, Inc.*, 827 F.3d 1052, 1054 (Fed. Cir. 2016), *cert denied*, 137 S. Ct. 591 (2016). The implications of whether an applicant provides notice of commercial marketing before FDA approval differ depending on whether the applicant chooses to participate in the patent dance and how many steps of the dance it

completes. *See* slip op. at 4-7 (describing the steps in the patent dance).

If an applicant opts to skip the patent dance entirely, it gives up control over the timing of subsequent litigation. *See* slip op. at 7-8; 42 U.S.C. § 262(l)(9)(C). In this case, there seems to be no apparent adverse consequence to providing early notice. Regardless of when the applicant provides notice of commercial marketing, it cannot initiate a declaratory judgment lawsuit to resolve issues of infringement and validity—only the sponsor can sue, and may do so at any time and on any patents claiming the biologic product or a method of using the biologic product. *See* slip op. at 7-8; 42 U.S.C. § 262(l)(9)(C). Similarly, if the applicant starts the patent dance but quits early, the sponsor may bring a declaratory judgment action on any of the patents on its original list plus any later-acquired patents. *See* slip op. at 7-8; 42 U.S.C. § 262(l)(9)(B). If the applicant gives early notice under these circumstances, it may potentially begin selling its biosimilar product immediately after FDA approval, although it risks having to pay damages if the sponsor sues and wins. The Supreme Court did not address whether the sponsor would be able to obtain a preliminary injunction preventing the applicant from selling its product. Although the statute only addresses a preliminary injunction in the context of the patent dance, a sponsor would likely seek to enjoin marketing of the biosimilar product in the same way any patent holder might enforce its patent rights.

On the other hand, if an applicant elects to provide the sponsor with a copy of its application and manufacturing information and then completes the patent dance, early notice could lead to overlap of the two phases of biosimilar litigation. The first phase will occur after the application is filed, the lists of patents are exchanged, and the patents to be litigated are identified. 42 U.S.C. § § 262(l)(6)(A), (B). Once the applicant provides its notice of commercial marketing, then either party may commence the second phase by bringing a declaratory judgment suit relating to infringement, validity, or enforceability of any patents on either party's list but not part of the phase-one litigation, including any newly issued or in-licensed patents. *See* 42 U.S.C. § § 262(l)(7), (8), (9)(A).

Because the second phase of litigation is triggered by the applicant's notice of commercial marketing, the applicant who participates in the patent dance controls the timing of initiation of the second phase. 42 U.S.C. § 262(l)(9)(A). One area where this may be used to the applicant's advantage is for newly issued or licensed patents, which were not available for litigation in phase one. Once the applicant has provided its notice of commercial marketing, it may sue for declaratory judgment relating to these newly issued or licensed patents. Being able to provide early notice of commercial marketing, as allowed under the Supreme Court's decision, provides the applicant the ability to time the second phase such that these additional patents are litigated before the biosimilar application is approved, allowing the applicant to market its product earlier and closer to the expiration of the 12-year regulatory exclusivity than it would otherwise be able to do, without risk, if litigation could not commence until after the application was approved.

The clearest outcome of the decision is that the sponsor is not entitled to an additional 180-day exclusivity after the 12 years granted by the statute. An additional result of the decision is that an applicant who participates in the patent dance can advantageously initiate litigation on newly issued or in-licensed patents of the sponsor before obtaining FDA approval, allowing earlier resolution of potential patent issues and, thus, earlier possible market launch of its biosimilar product.

One potential unresolved issue with early notice of commercial marketing is what constitutes effective notice. This issue is currently being disputed in *Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-839-RGA (D. Del.). Amgen contends that Hospira's notice of commercial marketing provided in April 2015 was not legally effective because, after that notice, the FDA issued a complete response letter to Hospira stating that its biosimilar application could not be approved in its current form, after which Hospira re-submitted its application. *See* Amgen's Amended Opening Brief in Support of its May 26, 2017, Motion for a Preliminary Injunction (Dkt. No. 277) in *Amgen Inc. v. Hospira, Inc.*, No. 1:15-cv-839-RGA (D. Del. June 29, 2017) at 10-11. The question remains: How effective

is notice of commercial marketing if the product as approved differs from that described in the application referenced in the original biosimilar application?

Conclusions

The Supreme Court held that federal injunctive relief is not a remedy for an applicant's failure to provide a sponsor with a copy of its biosimilar application and related manufacturing information. This holding is favorable to biosimilar applicants, as it permits them to elect to not fully engage in the patent dance. Likewise, the Court's holding that an applicant can provide notice of commercial marketing even before receiving FDA approval is favorable to biosimilar applicants as it provides additional control over the start of the second phase of litigation.

Although the Court answered questions about two key sections of the BPCIA, various issues are still unresolved. The consequences of the decision, even as to these two sections, remain uncertain pending remand and later district court interpretation of the ruling. In addition, potential FDA rule-making could influence how parts of the BPCIA are interpreted. Thus, we foresee more questions to be litigated, as would be expected with any complex new regulatory regime. We look forward to further judicial decisions answering these and other questions in the coming months and years.

The Federal Circuit Declares Upon Further Review - it's Very Obvious: *Soft Gel Technologies, Inc., v. Jarrow Formulas, Inc.*

Kevin L. Hardaway

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Introduction

On July 26, 2017, in Soft Gel Technologies, Inc., v. Jarrow Formulas, Inc. (Appeal No. 17-1051, Fed. Cir. July 26, 2017), the Court of Appeals for the Federal Circuit ("the CAFC") affirmed the Patent and Trial Appeal Board's (PTAB) rulings from three *inter partes* reexaminations invalidating numerous claims of three patents assigned to Soft Gel Technologies, Inc. ("Soft Gel") on obviousness grounds. The CAFC, in affirming the PTAB, applied various canons of obviousness law to refute Soft Gel's position, specifically emphasizing that an obviousness rejection cannot be overcome by attacking references individually, and that only a reasonably expectation of success, rather than absolute predictability of success, is required as a basis of motivation to combine references.

Soft Gel Patents

Each specification of the Soft Gel patents ("U.S. Patent Nos. 8,124,072 ("'072 patent"), 8,105,583 ("'583 patent"), and 8,147,826 ("'826 patent")) describes a method for dissolving a substance commonly referred to as CoQ10 in solvents known as monoterpenes. The patented inventions include a composition ("'583 patent"), a soft gelatin capsule ("'072 patent") and a method of making such a soft gelatin capsule ("'826 patent"), each claiming a solution of CoQ10 is dissolved in monoterpene. *Soft Gel Technologies*, Appeal No. 17-1051 at 3. CoQ10 is a coenzyme (i.e., a chemical compound that is required for the biological activity of certain proteins) which is necessary for certain metabolic processes. *Id.* Studies have shown CoQ10 to be effective in regulating blood pressure and cholesterol levels, as well as preventing various diseases such as certain types of cancers. *Id.* at 4. However, the Soft Gel patents indicate that CoQ10 is sparingly soluble in aqueous based solvents such as water, which limits the bioavailability of the coenzyme to the body. *Id.* As a solution for increasing the bioavailability of CoQ10 within the body, the Soft Gel patents describe the discovery of monoterpenes such as limonene, carvone, and derivatives thereof as solvents for CoQ10, with the amended claims of the Soft Gel patents specifically reciting a derivative of limonene identified as d-limonene. *Id.* at 4-6.

***Inter Partes* Reexamination**

On September 15, 2012, Jarrow Formulas, Inc. requested an *inter partes* reexamination of the Soft Gel patents, which was granted by the PTAB and resulted in the PTAB's rejection of almost all of the claims of the patents. During the *inter partes* reexamination, the PTAB identified and considered five key references for review against the claims of the Soft Gel patents.

The first reference considered by the PTAB was a Patent Application Laid-Open Disclosure No. S57-42616 ("Motoyama"). The PTAB found the Motoyama reference disclosed that CoQ10 is "highly soluble" in a particular monoterpene known as carvone. Specifically, Motoyama disclosed several examples in which CoQ10 was dissolved in l-carvone and placed in capsules which were administered to dogs with high indications of bioavailability within the animals. *Id.* at 7.

The second and third references considered by the PTAB contained overlapping disclosures: U.S. Patent No. 7,588,786 issued to Khan and Nazzal ("Khan '786 patent"), and a dissertation authored by Nazzal ("Nazzal"). The PTAB found that both references, similar to the disclosures of the Soft Gel patents, noted the poor solubility of CoQ10 in aqueous solvents such as water. Furthermore, each reference posited that solvents such as lipids or oils could be used instead. *Id.* To prove this premise, Nazzal and the Khan '786 patent both disclosed an experiment that demonstrated the melting temperature of CoQ10 could be lowered to the average human body temperature by mixing the coenzyme with a sufficient amount of solvents such as essential (volatile) oils including peppermint oil, spearmint oil, and lemon oil. *Id.* at 8. The Nazzal dissertation concludes with a list of six recommendations for future studies, one of which was to study the chemical components of essential oils such as limonene, menthone, and carvone for their potency in lowering the melting point of CoQ10. *Id.* at 8-9.

The fourth reference relied on by the PTAB was *Fenaroli's Handbook of Flavor Ingredients* ("Fenaroli"), which the PTAB found disclosed that lemon essential oils have many different components but contain approximately 90 percent limonene by weight. The fifth reference cited by the PTAB was a monograph published by the World Health Organization's International Agency for Research on Cancer ("IARC"). The PTAB found that monograph stated that limonene is "the most frequently occurring monoterpene." Furthermore, the PTAB found the monograph disclosed that limonene occurs naturally in the d- and l- forms, and that "the d- form comprises 98-100 percent of the limonene in most citrus oils." *Id.* at 10.

Based on these five references, the PTAB found grounds for invalidating various claims of each of Soft Gel patents on the basis of obviousness. In its ruling, the PTAB held that the combination of the five references suggests the invention claimed in each Soft Gel patent –i.e. using d-limonene (as Motoyama had used carvone) to dissolve CoQ10 for oral formulations. Further, the PTAB found a person of skill in the art ("POSITA") would have been motivated to combine those references and would have had a reasonable expectation of success in doing so. *Id.* at 11.

CAFC Analysis

On appeal to the CAFC, Soft Gel challenged three of the PTAB's findings during the *inter partes* reexaminations" 1) that d-limonene is the main constituent of lemon oil, 2) that the Khan '786 patent does not teach away from the claimed invention, and 3) that a POSITA would have had a reasonable expectation of success regarding the combination.

The CAFC began its analysis by setting forth two canons of obviousness law: "the question of whether a patent claim is invalid for obviousness under 35 U.S.C. § 103(a) requires consideration of the scope and content of the prior art, differences between the prior art and patent claim, the level of ordinary skill in the art, and any relevant secondary considerations,", and "[A]n obviousness determination also requires a person of skill in the art at the time of the invention to have had an 'an apparent reason to combine the known elements in the fashion claimed by the patent at issue,'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406, 418 (2007), and a "reasonable expectation of success" in doing so, *Alza Corp. v. Mylan Labs*., Inc. 464 F. 3d 1286, 1289 (Fed. Cir. 2006).

The CAFC refuted Soft Gel's first position and found that d-limonene is the main constituent of lemon oil. In support of its position, the CAFC agreed with the PTAB's finding that IARC and Fenaroli references disclosed that lemon oil consists of approximately 88 to 90 percent d-limonene by weight. *Soft Gel Technologies Appeal* No. 17-1051 at 12. Soft Gel provided an additional reference, which tested essential oil from a number of different lemon species and disclosed one sample in which the limonene

content was only 38.1 percent. However, the CAFC found this additional reference actually bolstered the PTAB's conclusions, as upon reviewing the testing of the other samples in the additional reference, the CAFC found that the amount limonene found in all of the samples discussed therein ranged from a minimum 38.1 percent to a maximum of 95.8 percent, and in each of the samples the amount of limonene was still much greater than that of any other constituent in the sample. *Id.*

Soft Gel advanced its second position that the Khan '786 patent teaches away from dissolving CoQ10 in lemon oil by arguing, *inter alia*, that the Khan '786 patent states that it is difficult to dissolve CoQ10 in lemon oil. However, upon a closer inspection of the Khan '786 patent, the CAFC found the reference actually discloses that CoQ10 is difficult to dissolve in aqueous solvents and fixed (*nonvolatile*) oils, and in lieu of using these types of oils to dissolve CoQ10, essential (*volatile*) oils such as lemon, peppermint, or spearmint oils should be used as a solvent for CoQ10. *Id.* at 13. The CAFC further indicated that Soft Gel's approach of attacking an individual reference in the context of making a teaching away argument was improper as "non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *See In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The CAFC found that, when read together, the Khan '786 patent and the Motoyama reference suggest using the monoterpenes in lemon, peppermint, and spearmint oil in conjunction with CoQ10. *Id.* at 14-15.

In advancing its final position that a POSITA would not have had a reasonable expectation of success in combining the references to use d-limonene in Motoyama's invention, Soft Gel argued, *inter alia*, that neither the Motoyama, Nazzal, nor the Khan '786 patent expressly mentioned d-limonene, and therefore a POSITA would not have expected d-limonene to function like the carvone disclosed in Motoyama. The CAFC countered that position by indicating that Soft Gel had ignored the fact that the main constituent of lemon oil as used in Nazzal and the Khan '786 patent is d-limonene, as well as the recommendation in the Nazzal reference to further study the interaction that exists between CoQ10 and essential oils, specifically the chemical components of essential oils such as limonene, menthone, and carvone. *Id.* at 15.

Based upon these teachings, the CAFC held that a POSITA having the benefit of these references would be motivated to combine them as (1) Nazzal suggests testing the interaction of carvone and CoQ10 as well as the interaction of limonene and CoQ10, and (2) Motoyama teaches that carvone successfully dissolves CoQ10. Thus, a POSITA would reasonably expect that limonene, like carvone, would successfully dissolve CoQ10, and further would reasonably expect d-limonene to work consistent with Nazzal's recommendation to study limonene based on his testing of lemon oil, of which d-limonene is the main constituent. *Id.* at 15-16.

In further support of the position that there was no reasonable expectation of success in combining the references, Soft Gel additionally presented an article, co-authored by Khan after the issuance of the Khan '786 patent and the publication of the Nazzal dissertation, which evaluates methods of delivering d-limonene to the body. Soft Gel posits that the reason Khan conducted the follow up research was because it must not have been obvious that the lemon oil results in his earlier experiments were attributable to d-limonene. *Id.* at 16. In response to this position, the CAFC conceded that while the Khan '786 patent explicitly discloses lemon oil in lieu of d-limonene, this did not give rise to the inference that a POSITA would not expect d-limonene, the main constituent of lemon oil, to operate in the same manner, and suggested Khan may have had just that expectation when conducting his subsequent research.

The CAFC further indicated that by making this argument, Soft Gel advanced an incorrect legal standard for obviousness which requires "absolute predictability" rather than a reasonable "expectation of success". *Noelle v. Lederman*, 355 F. 3d, 1343, 1352 (Fed. Cir. 2004) Furthermore, the CAFC stated that a supplemental study does not imply lack of awareness of the likely result; rather, studies are frequently conducted to confirm what is suspected to be true. *Soft Gel Technologies* Appeal No. 17-1051 at 16.

Conclusion

This case demonstrates that patent practitioners must be (1) conscientious when choosing evidence to support their positions, and (2) aware of the proper legal standards that either support or refute their

positions. In this case, there were many instances where Soft Gel cited passages in a reference that on their face seemed to support their position. However, upon a closer inspection of the entire reference, it became clear that the reference did not actually teach what Soft Gel proposed it did. Further, Soft Gel erred in failing to properly consider canons of obviousness law in making the arguments to support their position, as evidenced by the CAFC underscoring that an obviousness rejection cannot be overcome by attacking references individually, and only a reasonably expectation, rather than an absolute predictability, of success is required as a basis of motivation to combine references.

Portland Rockers Score a Winning Touchdown for the Redskins in Supreme Court Trademark Dispute

Jason P. Bloom and Wesley Lewis

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On Monday, the Supreme Court issued its decision in *Matal v. Tam*,[1] a high-profile dispute implicating NFL football, Portland dance-rock, and the Lanham Act's disparagement clause. In its eagerly anticipated decision, the Court, voting 8-0, struck down the Lanham Act's prohibition on disparaging trademarks as facially unconstitutional under the First Amendment. The ruling is being hailed as a significant victory for Simon Tam and his band, the Washington Redskins organization (whose trademark registrations had been canceled pursuant to the now-unconstitutional clause), and free-speech advocates everywhere.

The dispute centered on Tam and his band, The Slants. The term "*slant*" is considered a racial epithet for people of Asian descent, but Tam and his bandmates—all of whom are Asian-American—claimed to adopt the moniker in an effort to lessen the derogatory connotation of the word by "reclaiming" it. Tam sought federal trademark registration for THE SLANTS. Due to the term's use as a slur, the Examining Attorney refused the application under Section 2(a) of the Lanham Act, which prohibits registration of disparaging, immoral, and scandalous marks. Both the Trademark Trial and Appeal Board (TTAB) and the Federal Circuit affirmed the refusal to register, but an *en banc* panel of the Federal Circuit reversed, holding that the prohibition against the registration of disparaging trademarks was, in fact, an unconstitutional restriction on speech.

In an opinion by Justice Alito, the Supreme Court affirmed the Federal Circuit's *en banc* decision, finding that "trademarks are private, not government speech," and holding that Section 2(a)'s viewpoint-based regulation of speech did not pass constitutional muster. The Court rejected the attempt by the U.S. Patent and Trademark Office (USPTO) to characterize trademark registration as government speech. Unlike the specialty license plates at issue in *Walker v. Sons of Confederate Veterans*, the Court determined that trademark registration does not convey a Government message or carry with it an association "in the public mind" with the State.[2] "If the federal registration of a trademark makes the marks government speech," the opinion quipped, "the Federal Government is babbling prodigiously and incoherently."[3]

Throughout the opinion, the Court expressed serious concerns about the potential for misuse of an over-expansive concept of government speech. "If private speech could be passed off as government speech by simply affixing a government seal of approval, government could silence or muffle the expression of disfavored viewpoints."[4] The Court pointed out that the USPTO's interpretation of government speech might turn copyright law on its head, asking "[i]f federal registration makes a trademark government speech and thus eliminates all First Amendment protection, would the registration of a copyright for a book produce a similar transformation?"[5]

The Court similarly rejected the PTO's arguments based on "government-subsidy" and "government-program" cases. It distinguished trademark registration from government-subsidy cases since all of the government-subsidy cases relied upon by the PTO involved cash subsidies or their equivalent, whereas the federal registration of a trademark clearly does

not. As for the line of "government-program" cases, in which the government confers a substantial "non-cash benefit for the purpose of furthering activities that they particularly desired to promote" without providing a similar benefit for other activities,[6] the Court found that such cases "occupy a special area of First Amendment case law, and they are far removed from the registration of trademarks."

The Court then determined that the restriction on speech was viewpoint-based. Conceding that the disparagement clause "applies equally to marks that damn Democrats and Republicans, capitalists and socialists, and those arrayed on both sides of every possible issue," the Court nonetheless found that the prohibition constitutes viewpoint discrimination, in that "[g]iving offense is a viewpoint."[8] Having determined that trademark registration constitutes private speech, and that the disparagement clause was a viewpoint-based regulation on that speech, the Court struck down the Lanham Act's disparagement clause as facially unconstitutional.[9]

Of course, Tam's case is the lesser-known of two high-profile cases involving the Lanham Act's disparagement clause, the other being the cancellation proceedings surrounding the Washington Redskins' registered trademarks. Several of the Redskins' trademark registrations were canceled as disparaging. The Redskins filed an amicus brief in support of the Slants, and its parallel proceedings before the Fourth Circuit were postponed pending the decision in *Tam*. Now, the Fourth Circuit will presumably overturn the prior rulings and reinstate the team's trademarks.[7]

The broader impact of this decision remains to be seen. Elimination of the disparagement clause would arguably bring trademark law closer in line with patent and copyright registration regimes, neither of which imposes eligibility requirements based on the content or social desirability of a particular piece of intellectual property. It remains unclear, however, what impact the Court's disparagement ruling will have on the related Section 2(a) bars on registration of "immoral" or "scandalous" marks, which were not at issue in *Tam* and not specifically addressed. Given that trademarks are registered to enhance the market for one's goods and services, market pressure will likely continue to prevent disparaging, immoral, or scandalous trademarks from flooding the marketplace; if anything, the gatekeeping burden will simply shift from USPTO Examining Attorneys to consumers.

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[1] 582 U.S. ___ (2017) (slip op.). The case was previously captioned *Lee v. Tam*, but was updated to reflect the replacement of PTO Director Michelle Lee with Interim Director Joseph Matal.

[2] Slip op. at 16-17.

[3] Slip op. at 14-15.

[4] Slip op. at 14.

[5] Slip op. at 18.

[6] Slip op. at 21-22.

[7] Slip op. at 20.

[8] Slip op. at 22.

[9] In fact, the Court declined to decide whether trademarks are subject to the "relaxed scrutiny" of a *Central Hudson* analysis, since the disparagement clause would not be able to withstand even that. Furthermore, although it served as the basis for Judge O'Malley's concurrence during the *en banc* proceedings, the Court also conspicuously failed to address Tam's argument that the disparagement clause was void for vagueness, effectively leaving registrants at the mercy of individual examiners.

TC Heartland: What's the Big Deal?

Aaron C. Taggart

Aaron C. Taggart

If you haven't yet heard about the Supreme Court's decision in *TC Heartland v. Kraft Food Groups Brands LLC,* you're probably not a patent litigator. The case has been dominating legal industry headlines for months, and now that a decision has been issued, it is being hailed as the single most important case for patent litigators this side of *Markman v. Westview Instruments, Inc.* But is *TC Heartland* really a sea change for patent litigation? A review of Federal Circuit cases applying the portion of the patent venue statute not addressed by *TC Heartland* – what constitutes "a regular and established place of business" – indicates that the change may not be as sweeping as some have suggested.

Briefly, the *TC Heartland* decision addressed the test for proper venue in patent infringement suits for corporations. Until 1990, courts held 35 U.S.C. § 1400(b) to be the sole statute governing venue

for patent cases. That statute requires patent suits to be filed where the defendant "resides," or where the defendant "has committed acts of infringement and has a regular and established place of business." Interpreting 35 U.S.C. § 1400(b), courts found venue proper under the first prong only in states where the defendant was incorporated.

In *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990), the Federal Circuit held that the general venue statute, 28 U.S.C. § 1391(c), informed the meaning of "resides" as used in 1400(b), thus broadening its meaning to include all venues where personal jurisdiction is satisfied. Because the first prong of 1400(b) was then interpreted broadly, the second prong of that statute ("has committed acts of infringement and has a regular and established place of business") was rarely invoked.

The Supreme Court decision in *TC Heartland* overruled *VE Holding* and held that "'reside[nce]' in §1400(b) refers only to the State of incorporation." *TC Heartland*, slip op. at 10. Because the second prong of 1400(b) was not before the Court, what constitutes a "regular and established place of business" is left unresolved.

While decisions addressing the "regular and established place of business" prong under 1400(b) are few and far between, two pre-*VE Holding* cases are illustrative of how unpredictable the analysis of that prong may be going forward. In *In re Cordis*, 769 F.2d 733 (Fed. Cir. 1985), the Federal Circuit denied a petition for a writ of mandamus requiring the United States District Court for the district of Minnesota to dismiss the action for improper venue. As explained below, the facts of the case show that plaintiffs may face a low bar in establishing a defendant's regular and established place of business in a given venue.

The defendant Cordis was a Florida corporation, and was not registered to do business in Minnesota, and employed only two sales representatives there. *Id.* at 735. These employees worked from their homes, and Cordis did not lease or own any property in Minnesota. *Id.* Although it did not maintain a physical office in Minnesota, Cordis employed a secretarial service there for handling correspondence, including answering telephone calls and mailing sales literature. *Id.* Customers in Minnesota could obtain the product at issue either from Cordis' Florida offices, or from the Minnesota sales representatives, who maintained a stock of product in Minnesota for that purpose. *Id.* Perhaps significantly, the sales representatives also acted as technical consultants by advising customers on the use of the product at issue. *Id.*

The Federal Circuit denied Cordis' petition, and in doing so held that "the appropriate inquiry is whether the corporate defendant does its business in that district through a permanent and continuous presence there and not as Cordis argues, whether it has a fixed physical presence in the sense of a formal office or store." *Id.* at 737. Notably, the Court emphasized that "the remedy of mandamus is 'strong medicine' to be reserved for the most serious and critical ills, and if a rational and substantial legal argument can be made in support of the rule in question, the case is not appropriate for mandamus, even though on normal appeal, a court might find reversible error." *Id.* Accordingly, while the *Cordis* outcome could arguably be attributed more to the steep standard for mandamus than the underlying facts, it does appear that district courts will be afforded some leeway in deciding whether to maintain or dismiss the cases before them under the venue analysis.

The District Court decision in *Johnston v. IVAC Corporation*, 681 F.Supp. 959 (D. Mass. 1987) offers a contrasting analysis, reaching a different outcome on strikingly similar facts. Defendant IVAC was incorporated in Delaware, but was registered as a foreign corporation in Massachusetts. *Id.* at 960. It employed nine sales representatives who served Massachusetts, six of whom (including two[1] who sold the products alleged to infringe) resided in Massachusetts. *Id.* Similar to Cordis, the sales representatives worked from their homes, and IVAC did not own or lease any real estate in Massachusetts. *Id.* Likewise, IVAC sales representatives used a secretarial service in Massachusetts for answering calls and the like. *Id.* All sales orders were directed to IVAC's San Diego, CA office, and all sales were filled from product stocked in San Diego or other locations outside of Massachusetts. *Id.* Unlike *Cordis*, the sales representatives in Massachusetts only maintained a small number of products alleged to infringe for demonstration purposes. *Id.*

The *IVAC* Court found venue was improper in Massachusetts, specifically citing those few facts that distinguished *IVAC* from *Cordis*. *Id.* at 965. The Court noted that, unlike *Cordis*, "IVAC does not permit direct sales or keep any inventory in Massachusetts." *Id.* Furthermore, the Court emphasized that the sales representatives in *IVAC* "do not provide extensive technical support," which it found to be "vastly different from the operating room assistance presented by the salesmen in Cordis." *Id.*

The courts in *Cordis* and *IVAC* came to opposite conclusions on facts that appear to be very close, demonstrating just how unpredictable the interpretation of "a regular and established place of business" under 1400(b) is likely to be after *TC Heartland*. As courts begin scrutinizing that portion of the venue statute, it seems likely that results will vary from district to district and from judge to judge. Indeed, the Court in *IVAC* noted the "wide variety of opinions as to the type and extent of contacts which will satisfy the venue requirement." *IVAC*, 681 F.Supp. at 962. The *IVAC* Court, performing its analysis before *VE Holdings*, further noted that there was a split among the circuits as to whether a defendant must "maintain[], control[], and pay[] for a permanent physical location from which sales are made within the district." *Id.*

While the two cases noted here are not exhaustive, it appears that many open questions remain. For example, it is not clear now how non-sales activities in a given jurisdiction, such as training, manufacturing, and engineering, are evaluated in comparison to the sales activities the aforementioned cases scrutinized. The *Cordis* and *IVAC* cases suggest that perhaps other non-sales activities (e.g., the technical support provided by the representatives in *Cordis*) may weigh more heavily in favor of finding venue to be proper. As another example, it is unclear to what extent a virtual presence (e.g., websites and apps) may be taken into account for the venue analysis. Additionally, it is not apparent whether the location of a particular sale, for example under an analysis similar to those conducted in cases addressing extraterritoriality issues, may affect the venue analysis.

Just as courts have proven to vary in their application of *forum non conveniens*, we are likely to see a wide range of interpretations of 1400(b) post *TC Heartland*, with some courts more inclined to keep cases filed in their district than dismiss them. And while *TC Heartland* requires a new interpretation of the first prong of 1400(b), the second prong of that statute remains largely untested, making venue decisions unpredictable in the short term and perhaps leaving plaintiffs some flexibility in their choice of venue.

[1] One of the two sales representatives resigned after the suit was instituted. *Id.*

Supreme Court: U.S. Patent Rights May Be Exhausted Notwithstanding Post-Sale Restrictions or International Sales

Kenneth G. Parker, Tiffany Cooke and Michael D. Karson

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On Tuesday, the U.S. Supreme Court held that United States patent rights are exhausted by the sale of a product by the patentee or its licensee "regardless of any restrictions the patentee purports to impose or the location of the sale." *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, No. 15 1189, slip op. at 2 (U.S. May 30, 2017). In so doing, the Court reversed the Federal Circuit's February 2016, *en banc* decision. The case involved Lexmark's sale of printer toner cartridges with restrictions on resale and reuse of the cartridges. Companies that sell products with post-sale restrictions should review this holding and consider its ramifications prior to seeking to use patent infringement litigation to effectively enforce any such restrictions. Companies should review the content of

any written post-sale restrictions in light of the new ruling. Finally, companies that make sales abroad should consider the terms of their sales in light of the Court's holding that foreign sales can exhaust United States patent rights.

Like the Federal Circuit before it, the Supreme Court considered the application of the doctrine of patent exhaustion in two scenarios. First, the Court considered "whether a patentee that sells an item under an express restriction on the purchaser's rights to reuse or resell the product may enforce that restriction through an infringement lawsuit." *Id.* at 1. Second, the Court considered "whether a patentee exhausts its patent rights by selling its product outside the United States, where American patent laws do not apply." *Id.* at 2.

Lexmark "designs, manufactures, and sells toner cartridges to consumers in the United States and around the globe." *Id.* To address the business issue of remanufacturers acquiring, refurbishing, and reselling cartridges, Lexmark developed and manufactured patented cartridges equipped with a microchip that can communicate with a printer to prevent use of a refilled toner cartridge. *Id.* Lexmark sold these products to customers either at full price with no strings attached, or at a discount through Lexmark's "Return Program," which required customers to sign a contract "agreeing to use it only once and to refrain from transferring the empty cartridge to anyone but Lexmark." *Id.* Impression Products, a remanufacturer, acquired cartridges originally sold domestically and subject to Lexmark's Return Program, refurbished them to counteract the effect of the microchips, and resold those cartridges within the United States. *Id.* at 3. Impression Products also acquired cartridges originally sold abroad, refurbished those cartridges, and imported them into the United States for sale. *Id.*

Patent Exhaustion Applies Regardless of Restrictions on Post-Sale Use or Resale

The first issue addressed by the Supreme Court related to Lexmark's making and selling of refurbished printer cartridges that were originally sold within the United States and subject to Lexmark's Return Program. *Id.* at 1–2. On appeal, the Federal Circuit had declined to apply the doctrine of patent exhaustion to the Return Program cartridges, holding that "a patentee may sell an item and retain the right to enforce, through patent infringement lawsuits, 'clearly communicated, . . . lawful restriction[s] as to post-sale use or resale.'" *Id.* at 4. In so holding, the Federal Circuit reasoned that the exhaustion doctrine "derives from the prohibition on making, using, selling, or importing items 'without authority.'" *Id.* And, although "a patentee's decision to sell an item '*presumptively* grant[s] 'authority' to the purchaser to use and resell it,'" *id.* at 10, "the patentee does not have to hand over the full 'bundle of rights' every time." *Id.* Consistent with that logic, "the Federal Circuit concluded that Lexmark's sales had not exhausted all its patent rights, and that the company could sue for infringement when Impression Products refurbished and resold Return Program cartridges." *Id.*

The Supreme Court unanimously[1] reversed the Federal Circuit's holding as to the Return Program cartridges. E.g., *id.* at 13. Explaining that the Federal Circuit simply "got off on the wrong foot," the Court clarified that "the exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on 'on the scope of the *patentee's rights*.'" *Id.* at 9–10. Indeed, "[t]he right to use, sell, or import an item exists independently of the Patent Act" and a patent merely grants exclusionary power to "prevent others from engaging in those practices." *Id.* at 10 (citing *Crown Die & Tool Co v. Nye Tool & Mach. Works*, 261 U.S. 24, 35 (1923)). "Exhaustion extinguishes that exclusionary power." *Id.* (citing *Bloomer v. McQuewan*, 14 How 539, 549 (1853)).

Consistent with this approach, the Supreme Court clarified that a patentee may impose restrictions on its licensees, but such restrictions do not serve to "impose post-sale restrictions on purchasers that are enforceable through the patent laws." *Id.* at 11. Rather, "the only recourse for the licensee is through contract law, just as if the patentee itself sold the item with a restriction." *Id.* at 12.

The Supreme Court concluded that "Lexmark cannot bring a patent infringement suit against Impression Products to enforce the single-use/no-resale provision accompanying its Return Program cartridges. Once sold, the Return Program cartridges passed outside of the patent monopoly, and whatever rights

Lexmark retained are a matter of the contracts with its purchasers, not the patent law." *Id.* at 9. The effect of the decision here is that the authorized sale of a product that substantially embodies a patent exhausts the patentee's rights with respect to the article sold, regardless of any restrictions the patentee or its licensee attempt to impose. *Id.* at 13; *see also Quanta Comput., Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 637 (2008).

Patent Exhaustion Applies Regardless of the Location of the Sale

The second issue addressed by the Supreme Court related to Impression Products' importation into the United States of Lexmark toner cartridges originally sold abroad. *Id.* at 2, 13. Lexmark alleged, and the Federal Circuit had agreed, that "a foreign sale does not trigger patent exhaustion unless the patentee 'expressly or implicitly transfer[s] or license[s]' its rights." *Id.* at 13.

In a 7-1 decision, the Supreme Court reversed, holding that any sale, regardless of the location of the sale, triggers patent exhaustion. In so doing, the Court looked to analogous principles of copyright law and patent law's common "antipathy toward restraints on alienation." *Id.* at 13–14. The Court pointed to the "first sale doctrine" of copyright law codified at 17 U.S.C. § 109(a), noting that "the language neither 'restrict[s] the scope of [the] 'first sale' doctrine geographically,' nor clearly embraces international exhaustion.'" *Id.* at 13. The Court further relied on its decision in *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 538 (2013), in which the Court held that the "'first sale' [rule] applies to copies of a copyrighted work lawfully made [and sold] abroad." Impression Prods., No. 15 1189, slip op. at 14 (citing Kirtsaeng, 568 U.S. at 525). This is not the first time that the Court has looked to copyright law to inform a decision in patent law. *See SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods.*, LLC., 137 S. Ct. 954 (2017).

Applying these principles to patent law, the Court recognized that "nothing in the text or history of the Patent Act shows that Congress intended to confine that borderless common law principle to domestic sales." *Impression Prods.*, No. 15 1189, slip op. at 14.

In rejecting territorial limits on patent exhaustion, the Court reasoned that "[a] purchaser buys an item, not patent rights. And exhaustion is triggered by the patentee's decision to give that item up and receive whatever fee it decides is appropriate." *Id.* at 15. Indeed, "the right to exclude just ensures that the patentee receives one reward—of whatever amount the patentee deems to be 'satisfactory compensation.'" *Id.* at 15–16. Because Lexmark sold its cartridges, in the United States and abroad, its patent rights were exhausted. This result is consistent with the Court's analysis of the Return Program Cartridges—when it comes to patent exhaustion, "restrictions and location are irrelevant; what matters is the patentee's decision to make a sale." *Id.* at 18.

Conclusion

The Supreme Court changed the landscape of patent exhaustion with its ruling in *Impression Products*. Any company utilizing or attempting to enforce post-sale restrictions should review the decision and seek attorney input before proceeding with enforcement. Companies with foreign sales should also consider the effect of *Impression Products* on their domestic patent rights.

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[1] Justice Gorsuch took no part in the consideration or decision of the case. *Id.* at 18. Justice Ginsburg concurred in the Court's resolution regarding Impression Products resale of cartridges sold in the United States subject to Lexmark's Return Program.

Cisco Honors Haynes and Boone for "Excellence in Partnering"

Worldwide technology provider Cisco Systems, Inc. has selected Haynes and Boone, LLP for its Excellence in Partnering Award in recognition of the firm's stellar results on patent litigation and related issues.

In announcing the award, Cisco Vice President, Litigation Leslie McKnew thanked Partners David McCombs, Theo Foster, Andrew Ehmke and Ken Parker for their "incredible work" and said the team they led "has provided exemplary legal services and achieved significant successes in key matters" for the company.

Read more.

Haynes and Boone Partners Named America's Best Lawyers 2018

Best Lawyers®, published by Woodward/White, Inc., has named eight Haynes and Boone, LLP partners "2018 Lawyer of the Year." The following Haynes and Boone Intellectual Property lawyers were recognized this year:

David L. McCombs: Litigation-Intellectual Property
Jeffrey M. Becker: Trademark Law
Kenneth G. Parker: Trademark Law

Read more.

Haynes and Boone Partners Named California Rising Stars in 2017

Haynes and Boone, LLP Partners Kimberly Chase and Henry Welch have been named Rising Stars in California in the most recent Super Lawyers directory, published by Thomson Reuters.

Henry Welch, who is based in the Palo Alto office, is highlighted for intellectual property in Northern California.

Read more.

Haynes and Boone Secures Patent Trial Victory for Prinston Pharmaceutical

Haynes and Boone, LLP won a complete victory in New Jersey federal court for client Prinston Pharmaceutical Inc., a generic drug company.

Prinston is seeking to market a generic version of Brisdelle®, a non-hormonal (i.e., non-estrogen based) treatment for hot flashes associated with menopause. Plaintiff Sebela International Limited filed a Hatch-Waxman suit against Prinston and other drug companies, alleging they had infringed patents related to Brisdelle®.

Read more.

IP QUIZ

Trademark Trivia

Is there a likelihood of confusion?

Attempted registration of

for drinking water ("PURE HAWAIIAN WATER" disclaimed)

with the registered marks

("Hawaii Water" disclaimed)
for purified drinking water

and

PURE HAWAIIAN

(Supplemental Register)
for bottled drinking water

NO, according to the U.S. Trademark Trial and Appeal Board.

The Board reversed the refusal to register the mark PURE HAWAIIAN WATER (and design) covering drinking water, finding that the cited marks were inherently weak and entitled to a narrow scope of protection, and that consumer confusion was thus unlikely.

First, the Board found that the goods were legally identical, travel in the same channels, and to the same classes of consumers—all weighing in favor of a likelihood of confusion. Regarding the similarities of the marks, the applicant maintained that the Examining Attorney improperly focused on the wording of the marks while disregarding the colorful design and elaborate flowers, which serve to distinguish the respective marks. The Board disagreed, instead finding that the design element of the applied-for mark only emphasized the wording, and the respective design elements projected highly similar commercial impressions of a tropical mountain landscape. Due to the dominance of the wording in each mark, the Board found that this factor weighed in favor of a finding of a likelihood of confusion.

In reaching its conclusion, however, the Board found a single Du Pont factor—the strength of the marks—determinative of the case. The Board concluded that the literal portions of the mark were inherently weak, as evidenced by the applicant's disclaimer of the word "Pure Hawaiian Water," the disclaimer of "Hawaii Water" in the registered design mark, and that the registered PURE HAWAIIAN mark was registered on the Supplemental Register. Accordingly, the descriptive nature of the cited marks rendered them conceptually weak, indicating that consumers would look to other elements in the marks to distinguish between sources, and are thus likely to simply view Applicant's mark as "another entrant in to the consumer market for "Hawaiian" water. Thus, despite being highly similar marks for legally identical goods, the Board found that confusion was unlikely and reversed the refusal.

In re TOELL Co., Ltd., Serial No. 86888544 (August 1, 2017) [not precedential]

If you have any questions, please visit the Haynes and Boone Intellectual Property Law page of our website.

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